To: 5.1.2e [5.1.2e @aminoverse.com]
From: 5.1.2i
Sent: Sat 9/26/2020 12:16:32 PM
Subject: RE: Setting up lab for COVID 19 testing
Received: Sat 9/26/2020 12:16:39 PM

Dear 5.1.2e

Whether you can be added to the national capacity is in the hands of MoH and LCDK. Following a decision the process can be started.

To be added to the list of COVID-19 labs the labs should meet the requirements outlined in:

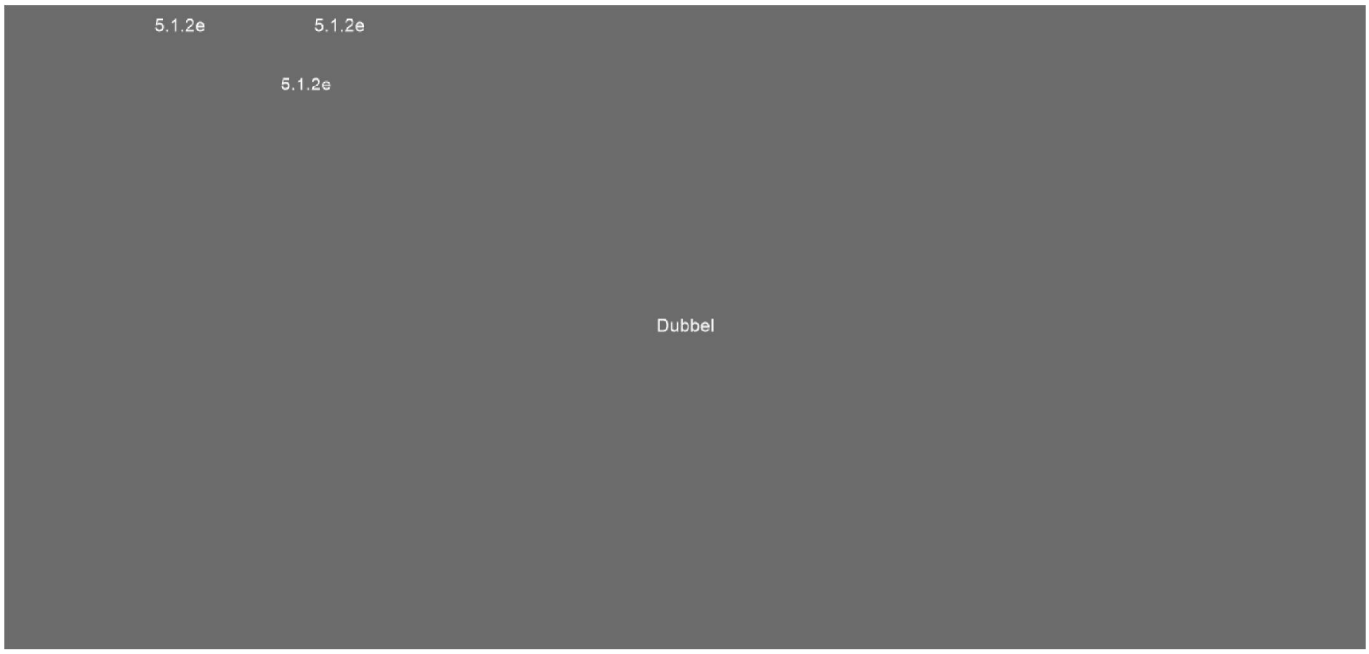
- https://lci.rivm.nl/covid-19/bijlage/aanvullend chapter 7
- https://www.nvmm.nl/vereniging/nieuws/nvmm-kwaliteitsdocument-covid-19-diagnostiek/

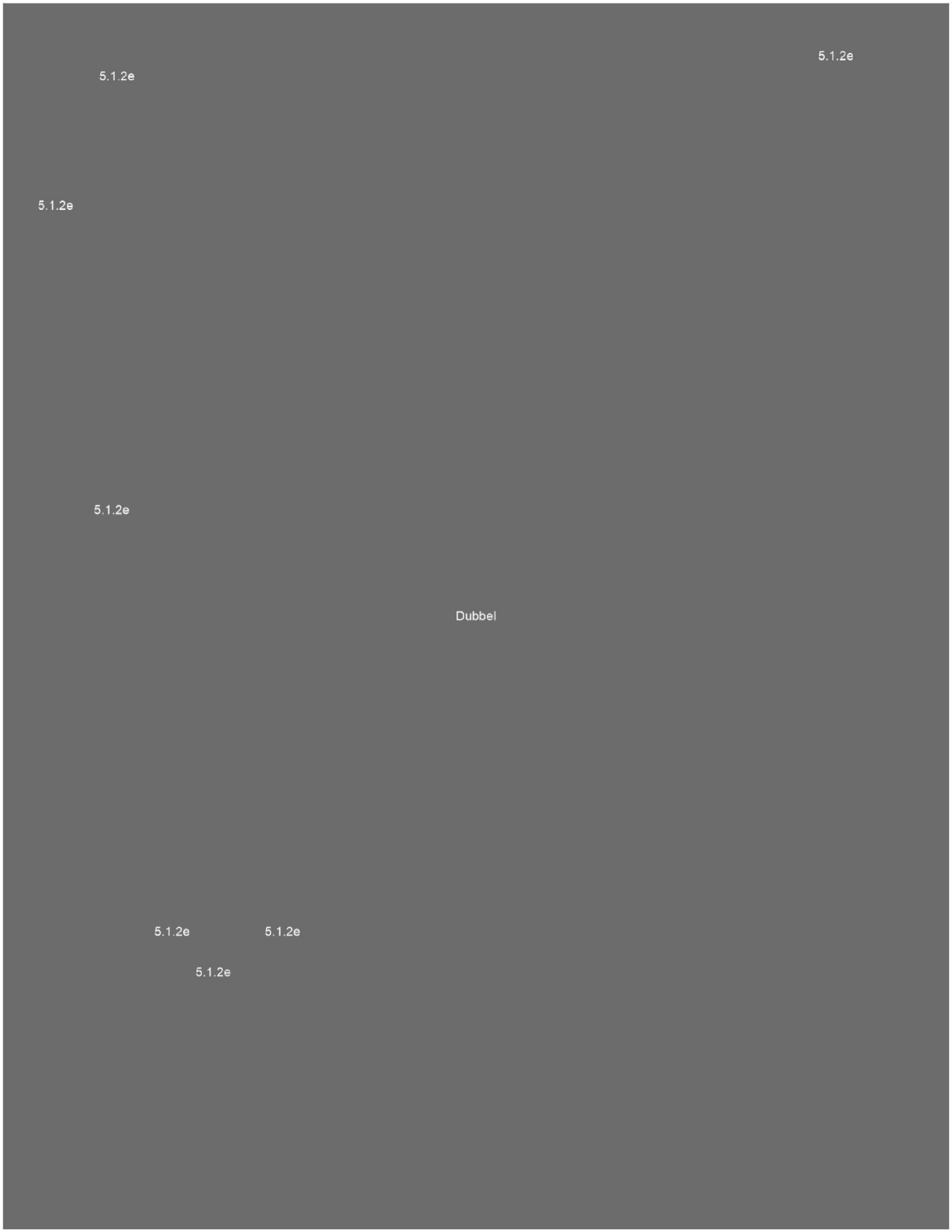
Briefly:

- Has ISO15189 accreditation or equivalent and in the scope RT-PCR or has other ISO accreditation that at least describes the procedures in the laboratory;
- Has the capability to process potential SAR-CoV-2 positive specimens safely at BSL-2 (ML-2) level
- Medical ultimate responsibility for issuing results is guaranteed;
- Successfully completed testing of quality panels for specificity and sensitivity SARS-CoV-2 consisting of simulated nose / throat clinical samples in virus transport medium with molecular amplification technique. With saliva as sample type also the saliva panel, and with pooling also the pooling panel. Panels should be tested with the workflow that is / will be used for testing patient materials;
- In addition to the panels, the first 5 positives, preferably with a representative Ct range, and 10 negatives from highly suspicious patients must be sent to RIVM for confirmation;
- After successfully completing the process with panels and confirmations, a declaration of performance will be issued and permission to independently perform COVID-19 molecular diagnostics;
- Connection with CoronIT realized
- Reporting to the Virological Day Report realized
- Obligate reporting positives to municipal health service (GGD) realized

Best regards,

5.1.2e

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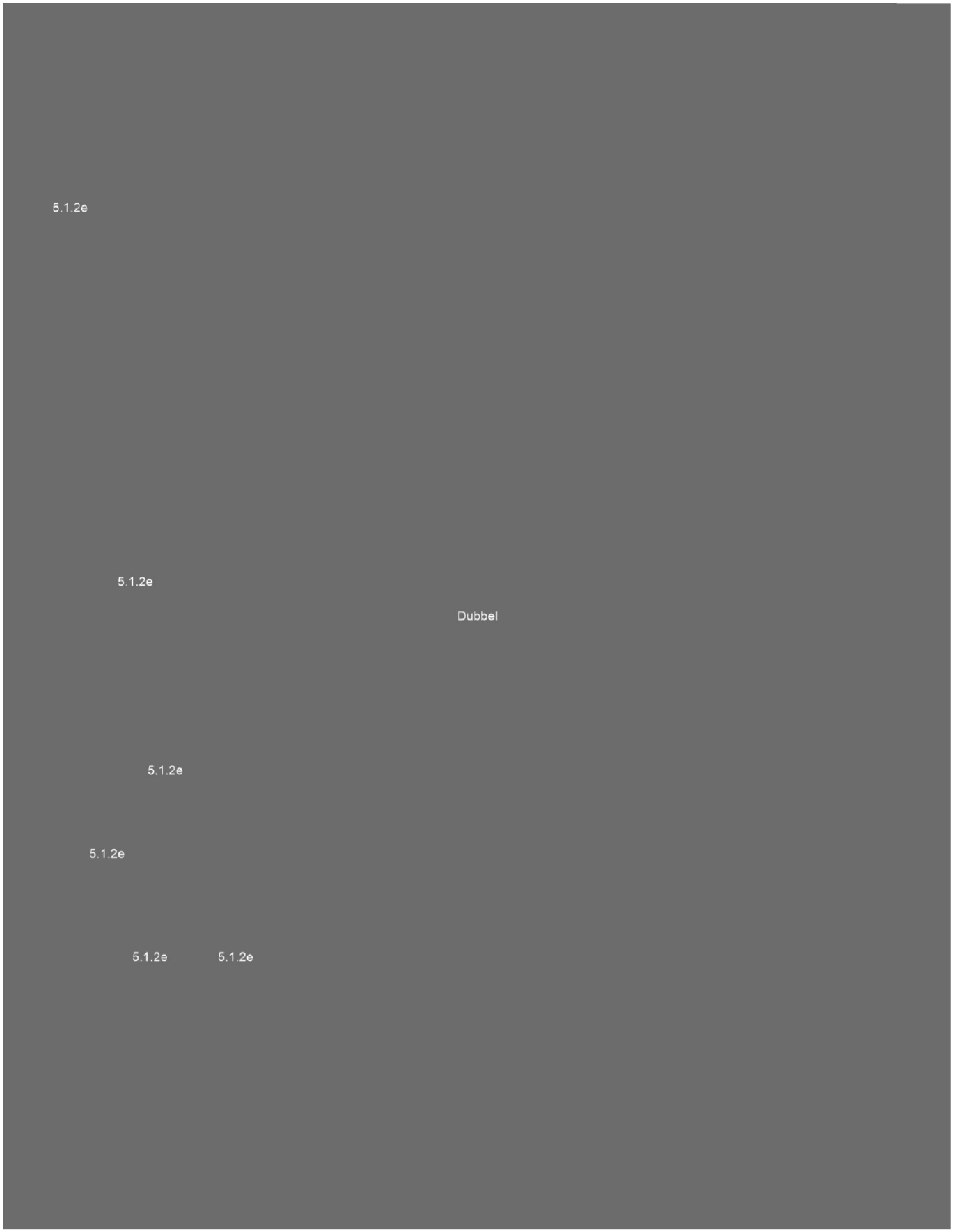
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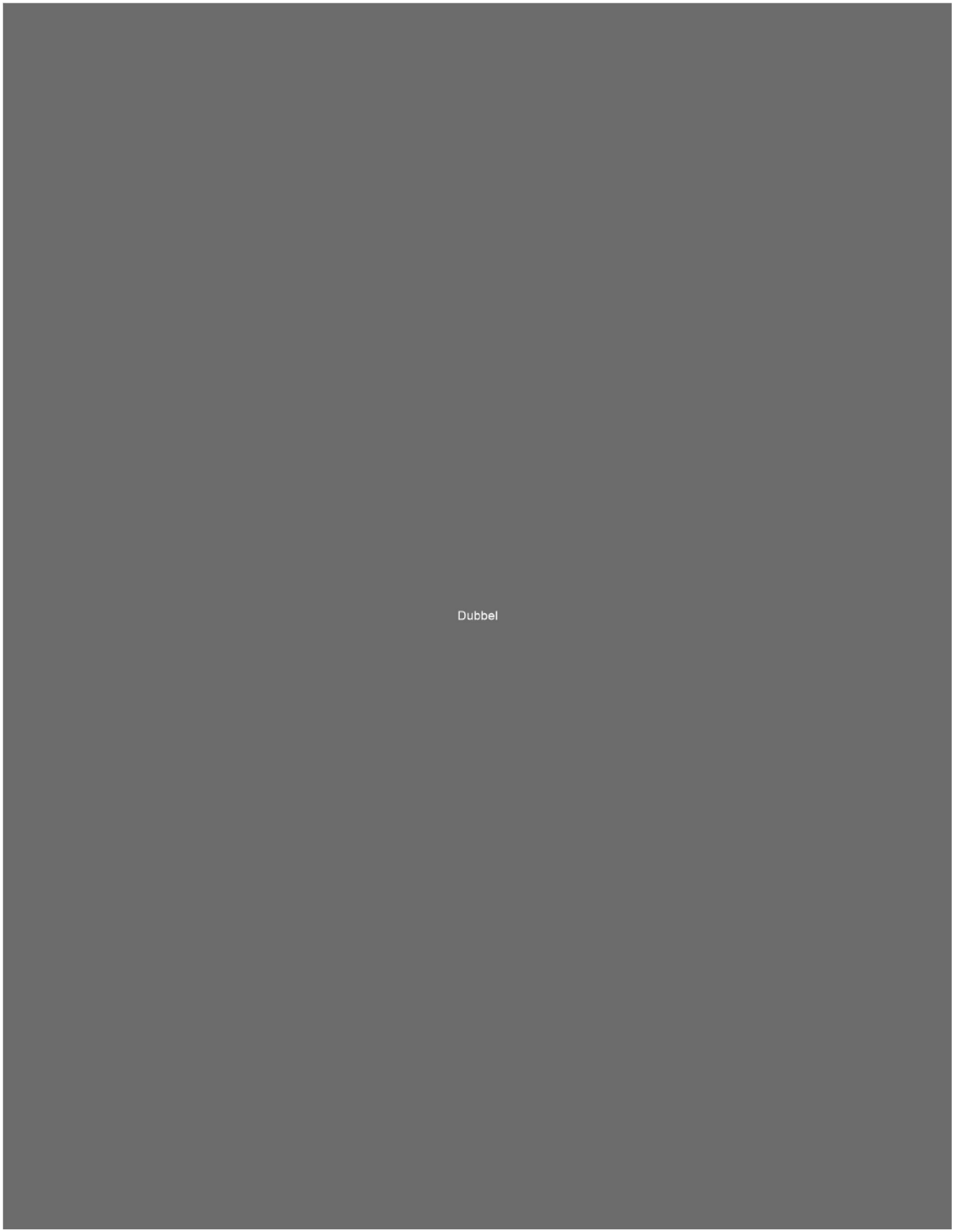
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